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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,826	02/09/2004	Barry N. Gellman	MIY-P03-006	9242

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EXAMINER

LUSTUSKY, SARA

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/774,826

Applicant(s)

GELLMAN ET AL.

Examiner

Sara Lustusky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 163-168, 170, 171, 173-180, 182-188, 190-198 and 200-202 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 163-168, 170, 171, 173-180, 182-188, 190-198 and 200-202 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/21/06, 09/13/04, 9/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The Examiner acknowledges Applicant's Amendment dated February 15, 2007. Claims 163, 175, 182, 185 and 193 have been amended. Claims 169, 181, 189, and 199 have been cancelled. Claims 163-168, 170-171, 173-180, 182-188, 190-198 and 200-202 are pending.

Information Disclosure Statement

In view of Applicant's arguments on page 6, the objections to the IDS set forth in the Office Action dated November 14, 2006 are withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 175-180 and 185-188 are rejected under 35 U.S.C. 102(b) as being anticipated by Adair (US 5336231).

Adair teaches a system (as seen in Figures 28-37) capable of treating urinary incontinence comprising:

- a. a shaft (92) having a curved portion (93) and an interlocking mating structure (96) on a distal end of the shaft (92); and
- b. a sling assembly (90) having an end for receiving the distal end of the shaft (92), and a complementary interlocking mating structure (84);

- c. wherein the interlocking mating structure (96) of the shaft (92) is inserted into the complementary interlocking mating structure (84) of the sling assembly (90);
- d. wherein the mating structures (96, 84) are releasably lockable such that the shaft (92) is releasable lockable to the sling assembly (90);
- e. wherein the sling assembly (90) is indirectly connected to the shaft (92) and the complementary mating structure (84) is indirectly connected to the sling assembly (90); and
- f. wherein the sling assembly (90) comprises a sling (82).

Claims 193-198 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (US 4935027).

Yoon teaches a system (as seen in Figures 1, 1E and 2A-10) capable of treating urinary incontinence comprising:

- a. a handle (20);
- b. a shaft (24a,b) attached to the handle (20) and having a channel (32) located at an end and a curved portion (as seen in Figure 1); and
- c. a sling assembly (30, 30_o, 30_i) having an end for associating with the channel (32) of the shaft (24a,b),
- d. wherein the channel (32) is releasable lockable for locking the end of the sling assembly (30, 30_o, 30_i) in the channel (32) (as described in lines 21-23, 57-58 of column 6, lines 1-19, 34-39, 60-68 of column 7 and lines 1-4 of column 8);

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- e. wherein the system further comprises a spring loaded locking mechanism (44, 150) for locking the end of the sling assembly (30, 30_o, 30_i) in the channel (32);
- f. wherein the sling assembly (30, 30_o, 30_i) comprises an elongated extension located at the end of the sling assembly (30, 30_o, 30_i);
- g. wherein the sling assembly (30, 30_o, 30_i) comprises a sling (as described in lines 9-11 of column 2);
- h. wherein in an alternate embodiment, the sling assembly (30, 30_o, 30_i) further comprises an aperture (as seen through 210) located at the end of the sling assembly (30, 30_o, 30_i) for advancing the sling assembly through the shaft (24b) (as seen in Figure 1E).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 182-184 and 190-192 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair (US 5336231) as applied to claims 175 and 185 above, in view of Wilkinson et al. (US 3580256).

Adair teaches a system capable of treating urinary incontinence comprising a shaft with a curbed portion and a sling assembly, wherein both the shaft and the sling

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assembly have interlocking mating structures, as described above. However, the use of a pouch over any portion of the sling assembly is not taught.

Wilkinson et al. teaches the use of a pouch or sheath with a sling material (as seen in Figures 1 and 7) to protect the body from the sling, wherein the pouch or sheath is flexible and can lay in a substantially flattened configuration (as described in lines 55-65 of column 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a pouch similar to that taught by Wilkinson et al. over a portion of a sling assembly similar to that taught by Adair because pouches or sleeves were commonly used in the art at the time of the invention to protect the body from implanted materials and objects.

Claims 163-168, 170, 171, 173-174 and 200-202 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US 4935027) as applied to claim 193 above, in view of Totakura et al. (US 5383904 A).

Yoon teaches a system capable of treating urinary incontinence as described above. While Yoon teaches that the sling assembly material comprises materials commonly used in the art, the use of a pouch over any portion of the sling assembly is not taught.

Totakura et al. teaches a sling assembly comprising a sling and a pouch or sleeve over a portion of said sling (as described in the abstract and in lines 31-52 of column 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a pouch similar to that taught by Totakura et al. over a portion of a sling assembly similar to that taught by Yoon in order to protect the tissues of the body from said sling as was a common combination used in the art at the time of the invention (as described in lines 11-15 of column 1 of Totakura et al.).

Response to Arguments

Applicant's arguments filed February 15, 2007 have been fully considered but they are not fully persuasive. On pages 7-8 Applicant addresses the rejections under 35 U.S.C. 102 over Adair and Yoon. Applicant states that sutures and suture materials are not equivalent to or interchangeable with the amended limitation "supportive sling". The limitation "a sling assembly including/comprising a supportive sling" in independent claims 163 and 175 does not describe the specific structure of the "supportive sling". A suture is fully capable and designed to provide support to the tissues of a patient. Applicant asserts that suturing of tissue is not synonymous with treating urinary incontinence. However, sutures were commonly used in the art at the time of the invention to provide tissue support to treat urinary incontinence. Additional references showing the use of sutures to treat urinary incontinence are cited below.

On page 9, with respect to claims 182-184 and 190-192 Applicant argues that the rejections set forth under 35 USC 103 over Adair in view of US 3580256 do not show all the claimed limitations in view of the previous arguments set forth by Applicant with respect to claims 175 and 185. However, in view of the above response regarding

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claims 175 and 185, Applicant's argument is not persuasive regarding claims 182-184 and 190-192.

On pages 9-11, with respect to claims 163-171, 1730174 and 200-202 Applicant argues that it would not have been obvious at the time of the invention to provide a protective pouch over a sling similar to that taught by Yoon. This argument is not persuasive in view of the teachings of Totakura et al. However, Applicant further argues that the particular pouch or sheath taught by Wilkinson would not fulfill a reasonable expectation of success if combined with a device similar to that of Yoon. This argument is persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Totakura et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lemay (US 5013292 A) (see Figures 5D-G) and Thompson (US 5697931 A) (see column 8 and Figure 2) teach the use of sutures to treat urinary incontinence.

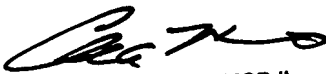
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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